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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,852	02/04/2004	Jeffrey W. Ruberti	20780-0006	9743

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EXAMINER

EGWIM, KELECHI CHIDI

ART UNIT	PAPER NUMBER
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1796

MAIL DATE	DELIVERY MODE
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04/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,852	Applicant(s) RUBERTI ET AL.	
	Examiner Dr. Kelechi C. Egwim	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 113-119 and 134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 113-119 and 134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/09/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/14/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 113-119 and 134 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an injectable solution comprising a polymer and being enabling for a crosslinked hydrogel formed by gelling the solution of polymer, does not reasonably provide enablement for an injectable **solution** comprising a crosslinked hydrogel. As a solution is, by definition, not a gel and the hydrogel is, by definition, not in solution, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to have, make or use a crosslinked hydrogel solution, commensurate in scope with these claims.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 113-119 and 134 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. While claim 113 and claim 114, from which the balance of the claims depend, each recite “an injectable solution ... comprising a physically crosslinked polymer hydrogels”, the claims also recite that “the polymer hydrogels gel in situ after injection”. It is unclear how the hydrogel, which is by definition already a gel and already crosslinked, is being defined as gelling only “in situ after injection”. It is unclear if applicant is claiming the ingestible polymer solution or the crosslinked hydrogel formed in situ after injection of the ingestible polymer solution.

Also, it is unclear how the crosslinked hydrogel, which is, by definition, out of solution, can be defined as being in solution.

Claim Rejections - 35 USC § 102/103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claim 113 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as being unpatentable over Hyon et al., or Yamauchi et al., for reasons cited in previous actions.

9. Claims 113-119 and 134 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as being unpatentable over Tanihara et al., Ku et al., Yao et al., or Okamura, for reasons cited in previous actions.

Response to Arguments

10. Applicant's arguments and declaration filed 02/14/2008 have been fully considered but they are not persuasive.

11. Regarding the argument that the examiner has not comprehended the distinction made between the prior art and the present claims, to the contrary it appears applicant is confusing what they believe the invention is with what they are actually claiming. As indicated above, there is a distinction, but it is between the injectable polymer solution and the gelled/crosslinked (physically or otherwise) hydrogel. Applicant seems to be confusing these two patentable distinct inventions, and the claims reflect this confusion (see above 112 rejections).

12. Regarding the intended use of the polymer solution in situ, a recitation of the intended use of the claimed invention must result in a structural difference between the

Art Unit: 1796

claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The claims are not to the use of the polymer solution, in situ or otherwise, but to the polymer solution itself.

13. Regarding Tanihara et al., the examiner disagrees with applicant's argument at a copolymer "cannot be simply described as 'PVA'" as this is common practice in the polymer sciences. Applicant has not defined their PVA to exclude copolymers and partially hydrolyzed forms of PVA. The Declaration does not undo this original presentation of the invention.

14. Regarding the argument that the "instant invention discloses methods to render [the PVA] gellable, applicant is reminded that the claims being prosecuted are to the polymer solution, and not the any method of using it.

15. Regarding applicant's attempts to draw distinction between the crosslinked hydrogel and the hydrogels of the prior art, again it appear applicant's arguments as inconsistent with what applicant is actually claiming, which at this point is indefinite. If applicant is claiming a solution that later gels (in situ or otherwise), then the comparison is between the ungelled solution of the present invention and ungelled solution of the prior art. If the claims are to the hydrogels, which would not be in solution, then the comparison would be between the present hydrogel and the hydrogel of the prior art. In

neither case would a method for gelling or crosslinking be required to be taught by the prior art. However, even the claimed subject matter is unclear.

16. Regarding “the injectability of the prior art hydrogels”, the claimed injectable solution, cannot at the same time be hydrogels. (see above 112's) The injectability would apply to the pre-gelled/pre-crosslinked prior art solutions, not the hydrogel of the prior art. The Declaration does not address this distinction.

Thus, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kelechi C. Egwim whose telephone number is (571) 272-1099. The examiner can normally be reached on M-T (7:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dr. Kelechi C. Egwim/
Primary Examiner, Art Unit 1796

KCE